SERIOUS, POSSIBLY ASSOCIATED AND UNEXPECTED ADVERSE EVENTS
REPORTED FOR HUMAN GENE TRANSFER PROTOCOLS
REPORTING PERIOD: 10/22/03 -- 01/27/04
RECOMBINANT DNA ADVISORY COMMITTEE MEETING
March 2004

Event #	OBA Date	Event Date	Protocol #	Event Description
			0009-412	**A Phase III, Multi-Center, Open-Label, Randomized Study to Compare the Effectiveness and Safety of Intratumoral Administration of RPR/INGN 201 in Combination with Chemotherapy Versus Chemotherapy Alone in 288 Patients with Recurrent Squamous Cell Carcinoma of the Head and Neck (SCCHN). Sponsor: Aventis Pharmaceuticals - Gencell Division**
5988	01/21/2004	01/06/2003		F/U from the Sponsor: Renal biopsy showed that the study participant had lupus and was started on medication to control this illness. Lupus not related to the gene transfer product.
			0102-458	**Pilot Phase II Study of Safety and Immunogenicity of a ALVAC-CEA/B7.1 Vaccine Administered with Chemotherapy, Alone or in Combination with Tetanus Toxoid, as Compared to Chemotherapy Alone, in Patients with Metastatic Colorectal Adenocarcinoma. Sponsor: Aventis Pasteur Limited.**
5874	11/21/2003	10/08/2003		Research participant was admitted with right upper quadrant pain, nausea and vomiting, dehydration, and mild fever. An intrahepatic abscess was identified and treated. The PI felt this may possibly be related to the study vaccine, chemotherapy, malignancy, or a prior hepatic abscess.
			0108-495	**A Phase I Trial of Recombinant Vaccinia Viruses that Express DF3/MUC1 and TRICOM (B7.1, ICAM-1, and LFA-3) in Patients with Metastatic Adenocarcinoma of the Breast.**
5877	11/21/2003	11/20/2003		Report that the research participant previously reported in Event 5876 expired due to progression of disease and the subject's demise was "unlikely" related to the investigational agent.
			0201-513	**Phase I Study of Intravenous DOTAP:Cholesterol-Fus 1 Liposome Complex (DOTAP:Chol-Fus 1) in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) Previously Treated with Chemotherapy.**
5864	11/17/2003	08/07/2003		Research participant admitted due to fever, generalized body aches, chest pain, dysuria, palpitations and coughing up of blood. Noted to have a low white blood cell count on admission, which the research participant has experienced with two prior gene transfer product infusions. As per the investigator, the low white blood cell count is due to a concomitant medication (steroids) and not due to the study agent.
5863	11/17/2003	09/24/2003		Research participant admitted due to fever, generalized body aches, chest pain, palpitations, and coughing up of blood. Noted to have a low white blood cell count which was deemed to be possibly related to the use of steroids but not due to the study agent.

Event #	OBA Date	Event Date	Protocol #	Event Description
			0203-519	**A phase II trial of CG8020 and CG2505 in patients with nonresectable or metastatic pancreatic cancer**
5819	10/21/2003	01/17/2003		This is the follow-up to Events 5360 and 5365. The limited autopsy revealed widespread pancreatic cancer, including abdominal carcinomatosis, pneumonia, and a hypercellular bone marrow without evidence of leukemia but consistent with a leukamoid reaction. This information coupled with previous measurements of GM-CSF levels led the Sponsor to deem the leukocytosis unrelated to the vaccinations and consistent with a leukamoid reaction.
			0301-568	**A phase II multi-center, double-blind, placebo-controlled, trial of VLTS-589 in subjects with intermittent claudication secondary to peripheral arterial disease**
5982	01/20/2004	01/03/2004		The research participant developed non-specific leg soreness, general malaise, and hiccoughs on Study Day 3. Continued nausea, vomiting, and diarrhea led to dehydration and hypotension requiring admission to the hospital on Study Day 19. The origin of symptoms remained undetermined at the time of this report and the work-up was continuing. The PI felt the symptoms were possibly related to the study agent, but additional information from the evaluation would be forthcoming.
			0302-571	**A phase II randomized study of GM-CSF gene-modified autologous tumor vaccine (CG8123) with and without low-dose cyclophosphamide in advanced stage non-small cell lung cancer**
5831	10/27/2003	09/01/2003		F/U from the sponsor (to event 5756): Autopsy showed widespread tumor involvement of all lung fields as well as areas of bleeding and dead lung tissue throughout. As per the investigator, a relationship of the events to the vaccine cannot be excluded. As per the sponsor, the cause most likely is a combination of an infection and spread of the tumor, but changes due to the gene transfer vaccine cannot be ruled out.
5870	11/19/2003	11/11/2003		Research participant died one day after surgical resection of tumor mass (in order to produce autologous vaccine product). Cause of death presumed to be acute myocardial infarction. Of note, the research participant never received gene transfer product.
5972	01/14/2004	12/30/2003		Two weeks after first vaccine injection the research participant presented with severe mental status changes and a markedly increased white cell count (including elevation of the eosinophil count). The investigator felt that the altered mental status was unrelated to vaccine and most likely related to use of pain medications (narcotics). However, cause of the white cell count elevation is not clear and possibly related to vaccine.
6010	02/11/2004	12/30/2003		F/U from the sponsor: Since the last report, the study participant has received two additional vaccinations with the GVAX product without any elevation of the white cell count being seen. Regarding the past adverse event, the initial white blood cell (WBC) count elevation that occurred 1-3 days after the first vaccination is believed by both the PI and sponsor to have been due to the vaccine product. However, what caused the markedly elevated WBC count (with elevation of eosinophils as well) that occurred approximately 2 weeks after the first vaccination is still not clear.